

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 11 1987

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

PMSD/ISB
1434

MEMORANDUM

SUBJECT: PP# 4F3074. Propiconazole (Tilt® or CGA-64250) on Meat of Livestock. Method Trial Request for Method AG-517. Accession No. 400527-1. RCB No. 1915.

FROM: Sami Malak, Ph.D., Chemist *Sami Malak*
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Donald A. Marlow, Chief
Chemical Operations Branch, BUD (TS-768)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

Note: This method trial request is to be expedited at the request of the Registration Division's Director, Mr. E. F. Tinsworth (Letter of 3/4/87)

Ciba-Geigy is proposing establishment of permanent tolerances for residues of propiconazole (Tilt® or CGA-64250), 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole, in/on meat of livestock. This method substitutes method AG-359 previously submitted in PP#4F3074, however, failed the trial (memo of R. Thomas to A. Smith, 9/9/86).

A method trial is requested for one chemical on three commodities. Samples should be run in duplicate at the requested fortification levels (see attached Table). Two copies of the appropriate method along with recoveries and sample chromatograms, are attached.

Please return the requested information on the attached forms and any other information concerning the method trial that we should be aware of including copies of chromatograms for representative controls, and fortified samples, standard curves and also submit examples of sample calculations.

The standard for CGA-64250 is available at the EPA Pesticides and Industrial Chemicals Repository under code F795 (Telephone No. 914/541-3951).

The Registration Division's "projected return date" for this action is April 24, 1987.

Please forward results of this method trial directly to Sami Malak.

Attachment 1: Two copies of Ciba-Geigy's Method No. AG-517 (43 pp), entitled: "Determination of Total Residues of Propiconazole in Meat, Milk and Eggs As 2,4-Dichlorobenzoic Acid By Capillary Gas Chromatography; January 9, 1987."

Attachment 2: Expedited memo from E. F. Tinsworth, 3/4/87.

cc With Attachments: D. Marlow

cc Without Attachments: RF, Circu, S. Malak, M. Bradley, Thompson, FDA, PP#4F3074, PM # 21, and MTO File.

RDI: P. V. Errico:3/11/87:R. D. Schmitt:3/11/87
TS-769C:RCB:CM#2:RM814A:S.Malak:X557-4379:3/10/87

Method: Ciba-Geigy's Method No. AG-517 (43 pp), entitled:
"Determination of Total Residues of Propiconazole in
Meat, Milk and Eggs As 2,4-Dichlorobenzoic Acid By
Capillary Gas Chromatography; January 9, 1987."

Do not use control values for recovery corrections.

Do not report control values as 0; if less than limit of
detection, report as such.

<u>Commodity</u>	<u>Chemical Added</u>	<u>PPM added</u>	<u>PPM found</u>	<u>% Recovery</u>
Beef Liver	Control	0.00		
	CGA-64250	0.10		
	CGA-64250	0.20		
Milk	Control	0.00		
	CGA-64250	0.02		
	CGA-64250	0.04		
Eggs	Control	0.00		
	CGA-64250	0.05		
	CGA-64250	0.10		

USE SEPARATE FORM FOR EACH METHOD

Modifications to method (major or minor):

Special precautions to be taken:

Source of analytical reference standards:

If derivitized standard used, give source:

Instrumentation for quantitation:

Instrumentation for confirmation:

If instrument parameters differ from method given, list parameters used.

Commercial source for any special chemicals or apparatus:

Comments:

Chromatograms:

1/20/87

VOLUME 1 OF 1 OF SUBMISSION

PROPICONAZOLE

STUDY TITLE

Determination of Total Residues of Propiconazole
in Meat, Milk and Eggs as 2,4-Dichlorobenzoic Acid
by Capillary Gas Chromatography

EPA Guideline 171-4

Author - P. J. Manuli

STUDY COMPLETED ON January 9, 1987

PERFORMING LABORATORY: CIBA-GEIGY Corporation
P. O. Box 18300
Greensboro, NC 27419

LABORATORY/STUDY NO. AG-517

Volume 1 of 1 of Study
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CIBA-GEIGY Corporation
P. O. Box 18300
Greensboro, NC 27419

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA section 10(d)(1)(A),(B), or (C).

Company: CIBA-GEIGY Corporation

Company Representative: Richard L. Conn

Date: 14 January 1987

Title: Senior Regulatory Specialist II

Signature: Richard L. Conn

These data are the property of the Agricultural Division of CIBA-GEIGY Corporation, and as such, are considered confidential for all purposes other than compliance with FIFRA section 10. Submission of these data in compliance with FIFRA does not constitute a waiver of any right to confidentiality may exist under any other statute or in any other country.

Statement Concerning Good Laboratory Practices

To the best of my knowledge, the study contained in this volume has been conducted in accordance with good and acceptable scientific practices. Because GLP's are not in effect for the study contained in this volume, certification of compliance with Good Laboratory Practices is not applicable.

L. Ballantine 1/14/87
Signature of Agent of Submitter/Sponsor

Larry G. Ballantine

Submitter/Sponsor:

Agricultural Division
CIBA-GEIGY Corporation
Post Office Box 18300
Greensboro, NC 27419

CERTIFICATION OF GOOD LABORATORY PRACTICE

To the best of my knowledge, the Good Laboratory Practice Statements found on Page 37 of this volume and signed by the Study Director, are truthful and accurate.

L. Ballantine
Signature of Agent of Submitter/Sponsor

Larry G. Ballantine

Date: 1/14/87

Submitter/Sponsor: Agricultural Division
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TILT CGA-64250 Reviews

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The next 39 page(s) is/are not included in this copy of the TILT reviews.

The material not included contains the following type of information:

- Identity of product inert ingredients
 - Identity of product impurities
 - Description of the product manufacturing process
 - Description of product quality control procedures
 - Identity of the source of product ingredients
 - Sales or other commercial/financial information
 - A draft product label
 - The product confidential statement of formula
 - Information about a pending registration action
 - Detailed methods and results of a registrant submission.
 - Duplicate pages.
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The information not included generally is considered confidential by product registrants. If you wish to obtain the information deleted, please contact the individual who prepared this response to your request.
